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Date	11/21/02		
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Re:	SN 09/964,120		

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## Message

Attached please find Response D to the Office Action dated May 14, 2003, including newly submitted claims 18-32:

Application No. 09/964,120  
Inventor: Marvin L. Schilling et al  
Filed: 9/25/2001  
For: Method for Producing Biologically Active Products

Examiner Sharmila S. Golumudi

Art Unit 1616

  
Bernd W. Sandt

**.IN THE UNITED STATES PATENT & TRADEMARK OFFICE6**

**Applicant:** Marvin L Schilling & Richard D. Farfard

**Serial No:** 09/964,120

**Filed:** 09/25/01

**For:** Method for producing Biologically Active Products

**Group Art Unit:** 1616

**Examiner:** Sharmila S Gollamudi

Hon. Commissioner of Patents  
& Trademarks,  
Washington, D.C. 20231

Sir,

**RESPONSE D**

In response to the Office Action dated May 14, 2003 please cancel the claims in the subject application and substitute the claims 18 to 35 set forth in the attached sheet.

Applicants have amended the claims in line with the suggestion of the Examiner to overcome the objection as to the scope of the claims. The applicants have also amended the claims to stress that the biologically active ingredients are recovered in unaltered form. Applicants have now limited the claims to protein containing substances and it is the proteins contained in these substances that constitute the biologically active substances. As is pointed out in Moore (of record here) these proteins exist in a water-insoluble form in nature and it is this form that is retained in applicants' process. This form is destroyed when the proteins are extracted since such involves solution of the protein. The only component of the composition removed is water. That water is not any

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added process water but water contained in the in the original natural product. The rest is retained in insoluble form in contrast to prior art, which extracts the proteins, i.e., dissolves the protein thus destroying the water-insoluble nature of the protein. By employing an ionic salt in combination with the antimicrobial agent applicants are able to retain the original structure while only removing the water through evaporation at slightly elevated temperatures. It is necessary in order to remove the water as quickly as possible to provide as large a surface area as is practical for the material to be comminuted before dehydration. The water content is based on the proteinaceous substance after comminution. Applicants have amended their claims to more clearly reflect such.

It is respectfully requested that the rejection of applicants new claims under 35 USC 103 as unpatentable over JP 59-088065 in view of Uono, US 4,789,497 be reconsidered particularly in the light of the amendments made to the claims.

The Japanese abstract discloses a process in which comminuted bone and marrow of animals is combined with a solution of lecithin and a solution of sodium hypochlorite and then further pulverized to an ultra-fine powder under temperature conditions to prevent the thermal denaturation of proteins. In a separate and subsequent step the powder is washed and then dehydrated to the "proper water content". However the reference fails to disclose what is meant by the term "proper". Thus the reference fails to teach that the water removed is that initially contained in the comminuted bone and marrow and not that added during the initial treatment. The reference states that the pulverization of bone material is done at thermal conditions which prevent denaturation. There is no teaching that the same limitation applies to the dehydration. The dehydration is not defined in terms of either conditions or result and in the absence of such there is no basis to conclude that the dehydration contemplated involves any protection against denaturation. Furthermore although the reference discloses the use of sodium hypochlorite, i.e. an antimicrobial agent, in the pulverization there is no teaching of such use in the dehydration step. Since the product is washed with water

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before it is dehydrated, there is no basis to assume that the hypochlorite used in the pulverization step is carried over into the dehydration step.

By itself the phrase "dehydrating to a proper water content" is meaningless. Neither method nor result is specified. The method could be merely draining the water off. There is no disclosure that the pulverized bone is heated. The proper water content could very well mean the water content of the original material is retained and that the only water removed is that of the added solutions, such removal would not prevent adverse microbial and pathogenic activity.

The reference therefore fails to disclose or suggest that the dehydration involves a thermal dehydration and specifically a thermal dehydration without denaturization. There is no suggestion that sufficient water is removed to prevent microbial or pathogenic activity. The water removed in applicants' process is that of the original product and not that of any added solution. There is no teaching of the use of an antimicrobial agent in the dehydration. Furthermore as the examiner concedes the reference fails to disclose the use of an ionizing salt. The examiner has imputed details to the vague process of the reference taken from applicants' teachings to support the rejection. It is submitted that such constitutes an improper extension of the reference and voids the rejection.

The secondary reference, Ueno, relates to dehydrating fish meat by mechanical means to produce a food product. The mechanical means employed are compression methods that squeeze out the water such as a sieve and a screw press (see examples). As is apparent from column 1, lines 14-43, the dehydration involved is that of water retained by the fish meat after being washed. The dehydration is carried out in the presence of both calcium or magnesium chloride and sodium chloride. The divalent calcium and magnesium salts are added to improve the dehydration process, however such addition causes denaturization due to the presence of calcium and magnesium ions. The denaturization is that of the mechanical properties of the fish meat defined as "ashi"

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(column 1, lines 61-68), not biologically active materials. To prevent that type of denaturization the patent teaches the use of both sodium chloride and magnesium or calcium chlorides.

Applicants submit that there is no basis for the combination of this reference with the Japanese abstract. They relate to different materials, different dehydration processes and different denaturization effects during dehydration. Thus if there is any teaching of denaturization during dehydration in the Japanese abstract, which applicants contest, it is that due to heating and is chemical in nature. The denaturization of the secondary reference is that due to the presence of calcium and magnesium ions and involves the mechanical properties of the product.

However even if the combination is deemed to be proper the secondary reference only extends the teaching of the primary reference with respect to a mechanical dehydration involving a denaturization of mechanical properties. There still is no suggestion that the dehydration should be carried out by thermal means under conditions that prevent chemical denaturization. Additionally the only water removed in the combination of the two references is that of water added as a result of the washing of the material, and not any water. There further is no suggestion of the use of an antimicrobial agent.

The combination of the Japanese abstract with Ueno fails to suggest the use of a thermal dehydration, sufficient to prevent decomposition as a result of microbial or pathogenic activity, in the presence of both an antimicrobial agent and an ionizable salt under conditions in which the original structure of the beneficial agents is retained in the dehydrated product.

Although all of applicants' dependent and subsidiary claims are believed to be patentable in view of the foregoing arguments, there are additional reasons why such claims are patentable.

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Thus claim 19 is deemed to be additionally patentable over the combination of the Japanese abstract and Ueno since neither of the references suggests the addition of the ionizing salt in solid form, an important feature considering the low moisture content desired. In both references the salts are added in the form of solutions. Claim 20 limits the process to a product having a water content of less than 15 % and an ionizable salt concentration of at least 15 by weight. The combination of the Japanese abstract and Ueno fails to suggest dehydration to 15 % and the use of an added ionic salt of 15% or more. The lowest water contents suggested by the combination are found in the examples of Ueno and are at least 70 % and the concentration of the added salts is stated to be in the range of 0.05 to 1.0 % of the solution added (claim 1), which even if totally incorporated into the fish meat is still less than 2 %, since the weight of the solution added is about twice that of the fish meat according to the examples. Furthermore claim 20 is deemed to be patentable over the combination of the Abstract and Ueno because none of the references teaches an upper temperature limit of 110° F in the dehydration to less than 15%.

For the same reasons as set forth with respect to claim 20, and claims 28-29 are deemed to patentable over the combination of the Abstract and Ueno. However in addition the claims 28-29 are further deemed to be patentable because neither reference suggests the dehydration of cartilage and more specifically chicken cartilage. Thus the Abstract relates to the pulverization of bone and marrow, which is not cartilage and very different in chemical composition and Ueno relates to the mechanical dehydration of fish meat.

Applicants submit that they have demonstrated the patentability of the claims over the references cited. The implementation of the vague and indefinite teachings of the Japanese abstract with the Ueno reference fails to suggest applicants' process in that Ueno does not involve a dehydration through heating.

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Applicants request that the claims be held allowable over the combination of the Abstract with Ueno.

Applicants' claims have also been rejected as unpatentable over GB 2114865 in view of Marat (US 3,878,107). The British patent relates to preparing a plant product, which includes heating up to 150° C. Maret, relates to the extraction of components contained in aloe gel after removal of the hulls from the leaves. The desired components in the resulting gel are extracted by reacting the gel with a solution containing citric acid, ascorbic acid glycine and phosphoric acid using ultraviolet light. As disclosed in column 3, lines 1-12, the process involves a stereochemical polymerization of the ingredients contained in the aloe extract catalyzed by UV radiation. Thus, there is a substantial change in the chemical structure of the extract. Any relationship to applicants' process is tenuous at best. The process of the reference is an extraction and not a dehydration. The chemical components of the original organic substance are drastically changed by means of a chemical reaction exactly the thing that applicants' process prevents. The amount of KCl used in the extraction solution is minimal and does not act as a stabilizer for the remaining insoluble product. Thus Maret adds nothing to the teachings of the British patent. Furthermore applicants claims are now limited to proteinaceous materials and thus exclude the plant materials of the references.

Applicants' claims have been rejected as unpatentable under 35 USC 103 as unpatentable over Ries (US 4,066,083) in view of Puppolo (US 5,562,535).

Ries discloses method for preparing an inert fibrous collagen that is used as a wound dressing or in other external non-digestive uses. The principal purpose of the method of purifying the fibrous protein structure to remove not only "non-collagen type ballast substances" but then treating the resulting tissue with proteolytic enzymes" and removing non-collagen type proteinaceous accompanying substances and telopeptides. The resulting product is then further purified by repeated solution and precipitation. At no point in the procedure is the water of the original material removed through heating.

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The procedure is clearly designed to remove any biologically active ingredients from the original substance and thus is the opposite of what applicants' process achieves.

The Examiner agrees that Ries does not specify the moisture content of the product and does not specify the method of dehydration used by applicants. As matter of fact Ries does not specify any method of dehydration of the original product and furthermore removes all active ingredients from the collagen.

Puppulo relates to the dehydration of shark cartilages using a particular drying technique. The drying technique used by Puppulo is preceded by an extraction technique that removes protein-containing ingredients. Applicants retain all proteins. Puppulo further fails to suggest the use of an ionic salt and an antimicrobial agent during the drying operation.

The combination of references fails to suggest applicants' dehydration process. Applicants further submit that the combination of references is improper since the treating processes involved are totally incompatible. There is no basis why a person skilled in the art would refer to Puppulo to modify the collagen extraction process of Ries.

Applicants' claims have been rejected over the combination of Ries in view of Puppulo and the Japanese abstracts. Ries freeze dries collagen after destroying or removing all biologically active materials and after having repeatedly extracted, dissolved and reprecipitated the original product. Puppulo similarly removes proteinaceous and other ingredients before drying. The Japanese abstract does not disclose the drying conditions set forth in applicants' claims. All three references are different purification processes and any feature of one would not suggest its use in any different process.

Allowance of the amended claims is respectfully solicited.

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Respectfully submitted,



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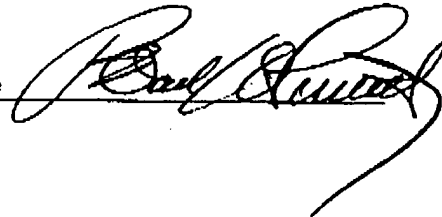
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I hereby certify that a copy of the foregoing Response has been forwarded to Group Art Unit 1616 to the attention Examiner Sharmila S. Gollamudi by facsimile on the date set forth below.

Date:

9/6/03

Signature



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